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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,907	07/25/2003	Mark Van Dyke	SwRI-2966-03	2421
21586	7590	11/06/2007		
VINSON & ELKINS, L.L.P. 1001 FANNIN STREET 2300 FIRST CITY TOWER HOUSTON, TX 77002-6760			EXAMINER KOSAR, AARON J	
			ART UNIT 1651	PAPER NUMBER
			NOTIFICATION DATE 11/06/2007	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/626,907	Applicant(s) VAN DYKE ET AL.	
	Examiner Aaron J. Kosar	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-220 is/are pending in the application.
- 4a) Of the above claim(s) 34-220 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :11/6/03; 2/24/04;
~~2/26/04~~; 3/08/04; 3/08/04.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of group I, claims 1-33 in the reply filed on July 31, 2006 is acknowledged. Applicant's election of the species of a metal (titanium) implant, bone morphogenic protein (BMP), and a keratin species of hair

Claims 34-220 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

Election was made **without** traverse in the reply filed on July 31, 2006 and, absent arguments in the election of species, in the election filed on October 1, 2007.

Claims 1-33 are pending and have been examined on their merits.

Information Disclosure Statement

The information disclosure statements (IDS) submitted on March 2, 2004, March 8, 2004, February 26, 2004, February 24, 2004, and November 6, 2003 have been considered and placed in the Application file; however, please note (as indicated by annotation in the IDS) that references which appear in a foreign language have been considered only to the extent of the figures and of the abstracts and accompanying translations which are in the English language and to the extent that the specification has indicated the content of the foreign language documents.

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Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 19-23, 28, 32, and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "reduced keratin" in claims 19-23 is a relative term which renders the claim indefinite. The term "reduced" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. One would not be apprised as to what compositions comprise "reduced keratin", because it is unclear how keratin is "reduced" *per se*. this ground of rejection may be overcome by amending *reduced keratin* to recite the *keratin which has been treated with a reducing agent*.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over KEN (US 20030004568 A1).

The claims are generally drawn to a device (composition) comprising a keratin-coated substrate. The dependent claims are further drawn to biocompatible materials, including species of titanium; bioactive factors.

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KEN teaches a device comprising a polymer and bioactive agent coating the device formed of a biocompatible material. Ken also teaches the device comprises a biocompatible material, including titanium (§ [0010]); a polymer, including keratin (§ [0013]); and, a bioactive agent, including a cell regeneration factor or a growth factor (§ [0014]).

It would have been obvious to use the components of the instantly claimed combination (titanium/keratin(/growth factor)), because Ken teaches a combination of biocompatible material:polymer and because Ken teaches a finite number of representative components useful in the invention, selected from the species comprising titanium:keratin(:growth factor). One would have been motivate to combine the species because Ken teaches that each of the species are useful for each of the respective components that comprise the invention taught by Ken. Additionally, because the success of the invention is determined only insofar as the components must be contacted, one would have had a reasonable expectation of success in making the claimed composition, especially in the absence of evidence to the contrary.

To the extent that the claims are drawn to a medical device, engineering construct, etc as recited in claims 2-3, the composition/device is not limited to the intended use of the composition. In the absence of evidence as to the criticality of a particular combination or element(s) within each of the disclosed intended uses correlated to specific combinations, proportions, or other undisclosed features of the instantly claimed invention, then the minimal requirement of the presence of the components would be sufficient to satisfy any/all of the claimed uses. Thus the compositions taught by the teachings of Ken would be obvious over the instant claims whereby the similar compounds of the instant claims versus those of Ken differ not structurally, but in the recited/intended use.

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Claims 1-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over HAMMER (US 20030220700 A1) in view of VAN DYKE (US 6,371,984 B1) or SUITA-MANGANO (Q1:PTO/SB/08A, 2/24/2004: EP 0298684 A2), and SAVAIDES (US 5617883 A)

The general teachings of the claims are above. The dependent claims additionally are drawn to bioactive factors, including the species bone morphogenic protein (BMP) and to the forms, species, and molecular weight of keratin.

HAMMER teaches a device/composition comprising a scaffold (part #20) and fixation component (part #30). Hammer also teaches that the #20 and #30 each comprising a limited number of known, representative species including titanium and the biopolymer, keratin, respectively (§ [0029]). Hammer further teaches combining polymer with an active agent, including the growth factor BMP (§ [0035]), and a composition which can be blended with keratin, including growth factors, including bone morphogenic proteins (BMP) (§ [0029], [0035]; figures).

VAN DYKE and SUITA-MANGANO teach that keratin may be obtained from a variety of tissues, including human hair (Van Dyke: column 2, ¶2; Suita-Mangano: page 2, ¶6, lines 34-43).

SAVAIDES teaches that hair keratin may be chemically treated to break and reform disulfide (cysteine) linkages present in the keratinous material by treating with reducing agents, including treating with thioglycolic acid, cysteine, or thiolactic acid (columns 1-2, various).

Although Hammer is silent regarding the specific combination titanium:keratin:BMP, it would have been obvious to make a titanium:keratin:BMP composition, because Hammer teaches a finite number of representative species comprising each of the individual components

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(titanium *or* keratin *or* polymers and blends (including keratin:BMP)), and because Hammer teaches that the compositions are useful for the same purpose (e.g. as scaffold components), it would be *prima facie* obvious to combine the elements so as to form the predictable composition comprising titanium, keratin, *and* BMP in a composition useful for a scaffold/fixation component.

Additionally, because the success of the invention is determined only insofar as the components must be contacted, one would have had a reasonable expectation of success in making the claimed composition, especially in the absence of evidence to the contrary.

To the extent that the instant claims are drawn to a medical device, engineering construct, etc as recited in claims 2-3, the composition/device is not limited to the intended use of the composition. In the absence of evidence as to the criticality of a particular combination or element(s) within each of the disclosed intended uses correlated to specific combinations, proportions, or other undisclosed features of the instantly claimed invention, then the minimal requirement of the presence of the components would be sufficient to satisfy any/all of the claimed uses. Thus the compositions of the instant claims whereby the similar compounds of the instant claims versus those of Hammer differ not structurally, but merely in the recited/intended use, would be obvious in view of the teachings of Hammer.

To the extent that the references are silent regarding the selection of a keratin species, the molecular weight properties, or the effect recited by the instant claims, it would have been obvious to one of skill to use keratin from a variety of sources, because keratin sources are well-known as taught by SUITA-MANGANO and because VAN DYKE teaches that keratinous material may be obtained from a variety of sources for use in implantable devices, including

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keratinous material from human hair. Again, because the success of the composition (the “device”) is dependent merely upon the ability of the contacting of the components especially in the absence of evidence to the criticality of a particular species of keratin source one would have had a reasonable expectation of success in combining the elements to include a keratin source including human hair in the device/composition.

It would have been obvious to use a keratin commensurate with the instantly claimed molecular weight range, because, although the cited art of HAMMER is silent regarding the recitation of a particular molecular weight of keratin, keratin would be expected to intrinsically comprise high-molecular weight keratin in the recited ranges. Furthermore, since the combination of elements of the device would have been obvious to one of skill, and because the coating effect appears to be dependent upon the combination of the elements, the combination of elements would thus be expected to intrinsically possess the claimed effect, especially in the absence of evidence to the contrary.

It would have been obvious to use a reduced keratin, because SAVAIDES teaches that reduced keratin is a known composition (e.g. permanent waved hair), and because selection of a hair from a reduced keratin would be a mere matter of judicious selection and would be routinely optimized by one of skill.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

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From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

The rejection above, under 35 U.S.C. 103(a), being obvious over, in part, in view of VAN DYKE has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) to the extent it reads upon Van Dyke might be overcome (in part) with respect to the reference of Van Dyke by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome to the extent it reads upon the art of Van Dyke by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

No claims are allowed.

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Conclusion

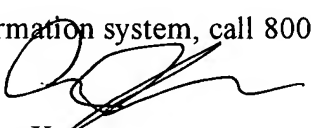
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

GODDARD (AV1: PTO/SB/08A, 2/24/2004) teaches that keratin may be treated with oxidizing agents or reducing agents. Goddard also teaches that oxidizing agents are not specific to the keratin disulfide linkages, attack multiple domains in the keratin molecule, and act slowly; whereas reductants "act very quickly and without bringing about any appreciable chemical alteration than that concerned with the sulfur." Goddard also teaches the reductant sodium sulfide.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron J. Kosar whose telephone number is (571) 270-3054. The examiner can normally be reached on Monday-Thursday, 7:30AM-5:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Aaron Kosar
Examiner, Art Unit 1651


SANDRA E. SAUCIER
PRIMARY EXAMINER